**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

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THIS DOCUMENT RELATES TO:

Cases Identified in Exhibit A
attached hereto

**ORDER ADOPTING**
**MEMORANDUM OPINION AND ORDER**
**(*Daubert* ruling re: Marc Toglia, M.D.)**

On October 23, 2017, plaintiffs filed a Notice of Adoption of Prior *Daubert* Motion of Marc Toglia, M.D. for Wave 6. [ECF No. 4856]. The court **ORDERS** that the Memorandum Opinion and Order (*Daubert* Motion re: Marc Toglia, M.D.) [ECF No. 2658] entered on August 25, 2016 as to the Ethicon Wave 1 cases is **ADOPTED** in the Wave 6[1] cases identified in Exhibit A. The Memorandum Opinion and Order (*Daubert* Motion re: Marc Toglia, M.D.) is attached hereto as Exhibit B.

The court **DIRECTS** the Clerk to file a copy of this Order Adopting Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 6 cases identified in the Exhibit attached hereto.

ENTER: July 31, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

[1] On Exhibit A, I have marked through cases that are closed on the inactive docket or assigned to another District Judge and any cases that could not be identified because of an error in the style or case number.

# EXHIBIT A

| | |
|---|---|
| ~~Felter, Diane~~ | ~~2:12-cv-08359~~ |
| ~~Selby, Connie~~ | ~~2:12-cv-09688~~ |
| ~~Hamlin, Teresa~~ | ~~2:13-cv-00522~~ |
| Ham, Delpha | 2:13-cv-01462 |
| ~~Meade, Deborah~~ | ~~2:13-cv-01744~~ |

EXHIBIT B

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

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THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

**MEMORANDUM OPINION AND ORDER**
**(*Daubert* Motion re: Marc Toglia, M.D.)**

Pending before the court is the Motion to Exclude the Opinions and Testimony of Marc Toglia, M.D. [ECF No. 2023] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

## I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

*Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

## II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

[1] The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2023-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by

precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witnesses—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

## III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

## IV. Discussion

Dr. Toglia is currently serving as the Chief of Female Pelvic Medicine and Reconstruction Surgery for the Main Line Heath System in Philadelphia. He is board-certified in female pelvic medicine and reconstructive surgery and obstetrics and

gynecology.

**a. Properties**

The plaintiffs seek to exclude Dr. Toglia's opinions regarding polypropylene safety, durability, biocompatibility, and materials because he is unqualified and has not employed a reliable methodology.

The plaintiffs argue Dr. Toglia is unqualified because he is neither a chemical nor biomechanical engineer and does not possess a "basic understanding of what is meant by the terms 'lightweight' and 'heavyweight.'" Mem. 7 [ECF No. 2028]. This challenge is without merit. Dr. Toglia is a board-certified urogynecologist who has performed thousands of SUI and POP surgeries over decades of clinical experience, in addition to conducting his own clinical studies on mesh products. This extensive clinical and research experience qualifies Dr. Toglia to opine on mesh's reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products. Moreover, the plaintiffs' disagreement with Dr. Toglia's characterization of the terms lightweight and heavyweight does not render Dr. Toglia unqualified to opine on mesh properties; such concerns are better suited for cross-examination. *See Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993)("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an opinion." (citing *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989))). The plaintiffs' Motion is **DENIED** on this matter.

It is not clear to the court on what grounds the plaintiffs are challenging reliability beyond asserting that Dr. Toglia is unqualified. Accordingly, insofar as the

plaintiffs' Motion is challenging the reliability of Dr. Toglia's opinions on polypropylene safety, durability, biocompatibility, and materials, it is **DENIED**.

**b. Complications**

The plaintiffs challenge Dr. Toglia's opinions regarding complications and complication rates. The plaintiffs object to Dr. Toglia's reference to his alleged high rates of patient follow up and low complication rate in his own clinical practice as having an unreliable foundation. When asked at his deposition how he keeps track of the products he uses, Dr. Toglia responded, "I have a very good memory." Toglia Dep. 65:22–24, Oct. 2, 2015 [ECF No. 2023-4]). When asked how he would determine which complications occurred with various products, Dr. Toglia responded:

> I would have to sit down and try and figure that out, counselor. I can't tell you off the top of my head that I have an accurate way of—I mean, there may be ways, through the billing system, to capture certain complications based upon—by diagnosis codes.

*Id.* at 69:12–21. Additionally, in response to a question at his deposition, Dr. Toglia stated that his practice has "a rate of follow-up that is over 90 percent." *Id.* at 163:11–12. In explaining what "records [he] would rely on to produce that," Dr. Toglia agreed with the statement that "someone would have to go through each record to determine when the patient last saw you, when she was contacted, what problems she was having." *Id.* at 162:1–11.

Dr. Toglia's statements suggesting he is simply making estimates and relying on "good memory" alone to recall the details of more than 2,500 surgeries demonstrate the unreliability of his opinions. "Good memory" may be sufficient in some circumstances to relate general conclusions, but not here. Just because a reliable

method exists to verify his opinions does not mean that a reliable method was actually employed. Accordingly, Dr. Toglia's opinions on complication rates and patient follow-up rates in his own practice are **EXCLUDED**.

The plaintiffs next assert that Dr. Toglia is unqualified to testify about the complication rates and risk of the Burch and autologous fascial sling procedures and that his testimony on this subject is unsupported by a reliable methodology.

It appears that the plaintiffs are challenging Dr. Toglia's qualifications on the basis that he has not used the Burch or autologous fascial sling procedures in his practice for at least the "last several years." He does not become unqualified to opine on the relative risks of a group of procedures because he has used his knowledge, experience, and judgment to stop using some of the procedures. Moreover, Dr. Toglia is not relying on personal experience alone; he has engaged in an extensive review of the scientific literature. Accordingly, to the extent the plaintiffs ask the court to find Dr. Toglia unqualified to testify about the risks and complication rates of alternative procedures, their Motion is **DENIED**.

Turning to reliability, the plaintiffs' argument that Dr. Toglia's opinions are not well-supported focuses on Dr. Toglia's inability to cite to specific studies during his deposition. Dr. Toglia evidently fumbled to find literature to support this opinion, taking nearly ten minutes to find a study that he believed supported his opinion. And the plaintiffs contend that the referenced study did not actually support his opinion. The plaintiffs overlook, however, Dr. Toglia's extensive and specific citation to scientific studies in his report. Dr. Toglia's failure to identify, on the spot, a study to

support a very specific sub-issue is not enough to undermine the reliability of his methodology as demonstrated in his expert report. Accordingly, to the extent the plaintiffs seek the exclusion of Dr. Toglia's opinions on complications rates and risks of alternative procedures as unreliable, the Motion is **DENIED**.

The plaintiffs also challenge the reliability of Dr. Toglia's methodology with respect to his opinion that there is no immunologic response to TVT. Dr. Toglia's difficulty naming studies on the spot during a deposition does not necessarily negate the studies and reasons articulated in his expert report. In his report, Dr. Toglia makes general reference to studies, meta-analyses, and systematic reviews; he also specifically cites several studies and explains that the studies are consistent with his own personal observations. The plaintiffs' objection addresses the weight, rather than the admissibility, of the opinion. Accordingly, to the extent the plaintiffs seek to exclude Dr. Toglia's opinions on immunologic response, their motion is **DENIED**.

**c. Warnings**

The plaintiffs claim Dr. Toglia is not qualified to offer expert testimony about product warnings, which includes expert testimony about the adequacy of the relevant Instructions for Use ("IFU"). According to the plaintiffs, Dr. Toglia is not an expert in the development of warnings labels and thus is not qualified to offer expert testimony about warnings. While an expert who is a gynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise*

*v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Toglia does not possess the additional expertise to offer expert testimony about what an IFU should or should not include.[2] Accordingly, Dr. Toglia's expert testimony about these matters is **EXCLUDED**.

**d. MSDS**

The plaintiffs seek to exclude Dr. Toglia's opinions related to the MSDS, specifically his characterization of the MSDS as regulatory paperwork, non-clinical, not relevant or reliable, and not something on which Dr. Toglia would rely in forming his opinions. The plaintiffs argue, with little elaboration, that Dr. Toglia is not qualified and his opinions are not based on any reliable methodology.

The plaintiffs have manufactured the problem they now ask the court to resolve. The opinions to which the plaintiffs object appear only in deposition testimony, and only in response to questions about the MSDS posed initially by the plaintiffs' counsel. Dr. Toglia does not include any MSDS opinions in his expert report, suggesting either Dr. Toglia does not intend to offer the opinions in question, or that they are subject to exclusion for his failure to disclose them pursuant to Rule 26. Either way, the plaintiffs' request for exclusion on reliability and qualifications

[2] In relation to the expert testimony about the adequacy of the IFU, Ethicon claims Dr. Toglia is qualified to testify about whether certain risks were commonly known in the medical community. In my view, this is not the subject of the plaintiffs' motion. The plaintiffs' motion focuses on whether Dr. Toglia is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Toglia may testify about whether certain risks were common knowledge. However, an expert cannot testify about whether any risks should have been included in an IFU unless he or she possess additional expertise—expertise Dr. Toglia does not possess.

grounds is moot and their Motion on this matter is **DENIED as moot**.

## V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these case, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard,* 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert

testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards

testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

*First*, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir.

2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

*Second*, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

*Third*, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

*Fourth*, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay.

The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

*Finally*, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

## VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude the Opinions and Testimony of Marc Toglia, M.D. [ECF No. 2023].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 25, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE